

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0327]

DDM

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Officer	A. Corbin

Agency Information Collection Activities; Proposed Collection; Comment Request; Blood Establishment Registration and Product Listing, Form FDA 2830

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to the blood establishment registration and product listing requirements and Form FDA 2830.

DATES: Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the **Federal Register**]*.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD

20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through

the use of automated collection techniques, when appropriate, and other forms of information technology.

Blood Establishment Registration and Product Listing, Form FDA 2830—21 CFR Part 607 (OMB Control Number 0910-0052)—Extension

Under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), any person owning or operating an establishment that manufactures, prepares, propagates, compounds, or processes a drug or device must register with the Secretary of Health and Human Services, on or before December 31 of each year, his or her name, place of business, and all such establishments submit, among other information, a listing of all drug or device products manufactured, prepared, propagated, compounded, or processed by him or her for commercial distribution. In part 607 (21 CFR part 607), FDA has issued regulations implementing these requirements for manufacturers of human blood and blood products.

Section 607.20(a) requires certain establishments that engage in the manufacture of blood products to register and to submit a list of blood products in commercial distribution. Section 607.21 requires the establishments entering into the manufacturing of blood products to register within 5 days after beginning such operation and to submit a blood product listing at that time. In addition, establishments are required to register annually between November 15 and December 31 and update their blood product listing every June and December of each year. Section 607.22 requires the use of Form FDA 2830, Blood Establishment Registration and Product Listing, for initial registration, for annual registration, and for blood product listing. Section 607.25 indicates the information required for establishment registration and blood product listing. Section 607.26 requires certain changes to be submitted as amendments to the establishment registration within 5 days of such changes.

Section 607.30 requires establishments to update their blood product listing information every June and December, or at the discretion of the registrant at the time the change occurs. Section 607.31 requires that additional blood product listing information be provided upon FDA request. Section 607.40 requires foreign blood product establishments to register and submit the blood product listing information, the name and address of the establishment, and the name of the individual responsible for submitting blood product listing information as well as the name, address, and phone number of its U.S. agent.

Among other uses, this information assists FDA in its inspections of facilities, and its collection is essential to the overall regulatory scheme designed to ensure the safety of the Nation's blood supply. Form FDA 2830 is used to collect this information.

Respondents to this collection of information are human blood and plasma donor centers, blood banks, certain transfusion services, other blood product manufacturers, and independent laboratories that engage in quality control and testing for registered blood product establishments.

FDA estimates the burden of this collection of information based upon information obtained from the Center for Biologics Evaluation and Research's database and FDA experience with the blood establishment registration and product listing requirements.

FDA estimates the burden of this collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	Form FDA 2830	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
607.20(a), 607.21, 607.22, 607.25, and 607.40	Initial registration	100	1	100	1	100
607.21, 607.22, 607.25, 607.26, 607.31, and 607.40	Reregistration	2,775	1	2,775	0.5	1,388
607.21, 607.25, 607.30, 607.31, and 607.40	Product listing update	180	1	180	0.25	45
Total						1,533

¹ There are no capital costs of operating and maintenance costs associated with this collection of information.

Dated: AUG 17 2005

August 17, 2005.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

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